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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/036,681 | 11/08/2001 | David G. Barkalow | 112703-198 | 4991 |

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EXAMINER

SHEIKH, HUMERA N

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1615

DATE MAILED: 08/22/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,681

Applicant(s)

BARKALOW ET AL.

Examiner

Humera N. Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003 (paper no. 11).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-43 is/are pending in the application.
- 4a) Of the above claim(s) 20-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-19 and 25-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Request for extension of time (2 months), the Request for Continued Examination (RCE) under Rule 1.114 and the Preliminary Amendment, all filed 05/27/03 is acknowledged.

Claims 16-19 and 25-43 are pending. Claims 16-19 have been amended. New claims 25-43 have been added. Claims 1-15 have been cancelled. Claims 16-19 and 25-43 are rejected.

This application contains claims (20-24) drawn to an invention non-elected with traverse in Paper No. 5. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 16-19, 25-39 and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyers (US Pat. No. 5,433,960).

Meyers discloses an edible film composition comprising edible *film-forming agents* consisting of effective amounts (~5 to ~25%) of celluloses, cellulose derivatives, starches, dextrans, maltodextrins, etc. and *combinations thereof* including at least two materials chosen from carbohydrates (derivatives), celluloses, gums (derivatives), proteins and lipids; *bulk filler agents* (5-95%) and *plasticizers* (~5 to ~15%) wherein the edible film composition also comprises at least one or more active agents located in the edible film, which include *dental agents* (i.e., plaque pH buffers/inhibitors, minerals, antimicrobial agents, microbial inhibitors, phosphates); flavor enhancers, sweeteners, softeners and antioxidants (see reference column 3, line 15 thru col. 14, line 18); (col. 6, line 20 thru col. 11, line 55) and claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meyers (US Pat. No. 5,433,960) in view of Zerbe et al. (US Pat. No. 5,948,430).

As discussed above, Meyers teaches an edible film composition comprising edible *film-forming agents* consisting of effective amounts (~5 to ~25%) of celluloses, cellulose derivatives, starches, dextrans, maltodextrins, etc. and *combinations thereof* including at least two materials chosen from carbohydrates (derivatives), celluloses, gums (derivatives), proteins and lipids; *bulk filler agents* (5-95%) and *plasticizers* (~5 to ~15%).

Meyers teaches that suitable water-soluble film forming agents include, asides from the celluloses and starches, edible polymers, edible plastics, low calorie bulking agents, vegetable gums, such as guar gum, locust bean gum, carrageenan gum, alginates, etc. The preferred water-soluble film forming agents are cellulose derivatives, which include ethyl cellulose, methyl cellulose, hydroxypropyl cellulose and sodium hydroxymethyl cellulose. The film-forming agent can be used in amounts of about 5% to about 25% (col. 6, lines 20-50). The ranges of film-forming agents taught by Meyers are overlapping ranges (instant range – ~10 - ~90%).

Bulk fillers, such as calcium carbonate, magnesium carbonate, talc and dicalcium phosphate are disclosed in amounts of between 5-95% at col. 9, lines 14-22.

According to Meyers, plasticizers are added to improve the flexibility of the film. Plasticizers mentioned herein include glycerin, polyethylene glycol (PEG), polyols and hydrogenated starch hydrolysates. The plasticizer may be contained in amounts of about 0.5-15% (instant range - <20%) (col. 8, line 7 thru col. 10, line 30).

Additionally, at least one or more active agents are included in the edible film forming composition, as delineated above.

Meyers teaches the use of various acids at col. 8, lines 5-11. Meyers is deficient only in the sense that he does not teach an acid from the selective group of claim 40.

Zerbe et al. teach a water-soluble film composition for oral administration comprising film-forming agents, fillers, plasticizers and flavor-enhancing acids, wherein suitable acids include tartaric acid and citric acid (col. 2, line 1 thru col. 3, line 40).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teachings of Zerbe within Meyers, because Zerbe explicitly teaches a water-soluble film forming composition comprising cosmetically active agents such as flavor-enhancing acids (i.e., tartaric, citric) to impart an enhancement of flavor to the composition and similarly, Meyers teaches an edible water-soluble film forming composition comprising active agents that include flavor enhancers and discloses various acids (i.e., stearic, lauric, palmitic, arachidic, oleic,

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linoleic and eladic acids). The expected result would be an edible film-forming composition capable of imparting enhancement of flavors and freshness of the mouth.

Response to Arguments

Applicant's arguments filed 05/27/03 have been fully considered but they are not persuasive. The applicant argued "Each of the pending claims now require at least two film forming agents, cellulose and starch. The art of record does not disclose nor suggest the claimed invention as set forth in each of the independent claims and claims dependent there from."

The applicant's arguments have been considered, but were not found to be persuasive. The examiner has currently rejected pending claims 16-19 and 25-43 over the references of Meyers ('960) and Zerbe ('430). The prior art clearly discloses and suggests an edible film composition comprising at least one of and combinations of celluloses and starches with bulk filler agents, plasticizers and active medicaments in similar ranges as instantly claimed. The prior art utilizes the same ingredients, in similar amounts for the same field of endeavor as the applicants. There is no significant distinction observed between the instant invention and the prior art since the limitations claimed are clearly suggested or taught by the prior art references. The applicants have not shown or demonstrated any unusual or unexpected results that accrue from the use of the instantly claimed ingredients or amounts. Meyers and Zerbe teach the generic

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concept of formulating edible film compositions that contain active ingredients to enhance or freshen breath (i.e., dental agents – plaque buffers & inhibitors, breath fresheners, antimicrobials). Hence the instant invention is rendered obvious and unpatentable over the prior art of record.


Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns
August 19, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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